REMARKS/ARGUMENTS

Reconsideration of this application, in view of the foregoing amendment and the following remarks and arguments, is respectfully requested.

Claims 1-10, 12-18 and 20 are currently pending in this application. By the foregoing amendment Claim 1 has been revised, and Claim 6 has been canceled without prejudice or disclaimer. Accordingly, Claims 1-5, 7-10, 12-18 and 20 remain in this application for consideration and allowance.

In the August 11, 2010 final office action the following claim objection and rejections, which are respectfully traversed for reasons subsequently set forth herein, were made.

- 1. Claim 6 was objected to under 37 CFR §1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim;
- 2. Claims 1-5, 7-9 and 12-15 were finally rejected under 35 USC §103(a) as being unpatentable over U.S. Patent 4,483,340 to Fogarty et al in view of U.S. Patent 5,090,957 to Moutafis et al;
- 3. Claims 7 and 10 were finally rejected under 35 USC §103(a) as being unpatentable over U.S. Patent 5,468,245 to Vargas, III in view of Fogarty et al and Moutafis et al;
- 4. Claims 16-18 and 20 were finally rejected under 35 USC §103(a) as being unpatentable over Vargas, III in view of Fogarty et al.

1. The 37 CFR §1.75(c) Objection to Claim 6

In the foregoing amendment this objection to Claim 6 has been overcome by canceling Claim 6 as required by the Examiner.

2. The 35 USC §103(a) Rejection of Claims 1-5, 7-9 and 12-15 Based On Fogarty et al In View Of Moutafis et al

Via independent Claim 1, each of applicants' Claims 1-5 specifies a tool for deploying an expandable structure into interior body regions comprising a catheter body defining an interior lumen and having a distal end opening through which a substance may be flowed outwardly from the interior lumen into an interior body region, and a stylet having a proximal end and being sized and configured for passage through the interior lumen, the distal end opening of the catheter body being configured to prevent outward movement of the stylet therethrough.

Representatively, but not by way of limitation, the claimed catheter body may be the structure 10 in applicants' FIG. 4, the interior lumen may be the lumen 24 in FIG. 4, the distal end opening may be the distal end opening 30 in FIG. 5, and the stylet may be the stylet 38 in FIG. 6.

On page 4 of the August 11, 2010 Final Office Action, the Examiner acknowledges that "Fogarty et al do not disclose the distal end opening through which a substance may be flowed outwardly from the interior lumen into an interior body portion". The correctness of this statement can be seen in Fogarty et al FIG. 3, which illustrates that the socket 34 does not extend clear through the Fogarty et al distal tip member 22, and thus cannot permit a substance to be flowed outwardly from the interior of the tube 24 into an interior body region.

The Examiner seeks to cure this deficiency in Fogarty et al using the Moutafis et al reference stating, on page 4 of the August 11, 2010 Final Office Action, that:

Moutafis et al. teach a similar distal end 230 of a catheter body having an opening 236a through which a substance may be flowed outwardly from an interior lumen into an interior body portion (Figures 3A-3B), while still preventing movement of a stylet 214 or 240 therethrough. It would have been obvious to one of ordinary skill in the art at the time of invention to provide a distal end opening through which a substance may be flowed outwardly, as taught by Moutafis et al., in order to facilitate delivery of fluids in the delivery site (col. 2, lines 39-50). (Emphasis added).

However, neither of the Moutafis et al elements 214 and 240 is a **stylet** as the Examiner contends. In ordinary and customary medical parlance, the accepted meaning of the term "stylet" is "a wire run through a catheter or cannula to render it stiff or to remove debris from its lumen", and the accepted meaning of the term "catheter" is "a hollow flexible tube for insertion into a body cavity, duct, or vessel to allow the passage of fluids or distend a passageway".

The Moutafis et al polyethylene tube 214 is thus clearly not a stylet, but is instead a catheter through which a fluid may flow. Similarly, the thrust insert member 240 has a tubular configuration and is thus also not a stylet. Accordingly, Moutafis et al, like Fogarty et al, fails to teach or suggest a distal end opening of a catheter body through which a substance may be flowed outwardly from an interior lumen into an interior body region and which is also configured to prevent outward movement of a stylet therethrough as recited in the present applicants' Claims 1-5, 7-9 and 12-15.

It should be further noted that even if the Moutafis et al tubular member 240 were to be characterized as a "stylet", it is disclosed in the Moutafis et al specification (beginning on line 1 of column 4) that the outer tube diameter of the thrust insert 240 is <u>matched to the inner diameter of the tube 214</u>. It thus appears in FIG. 3B that the outer diameter of the tubular member 240 is sufficiently small to permit the member 240 to pass distally outwardly through the opening 236a. <u>The Moutafis et al distal end opening 236a accordingly does not appear to be configured to prevent movement of the tubular member 240 outwardly therethrough as contended by the Examiner.</u>

Viewed from a somewhat different perspective, if an appropriately dimensioned true "stylet" were to be run distally through the Moutafis et al catheter tube 214 and associated tubular thrust insert 240 such stylet could clearly be passed outwardly through the distal end of the nosepiece passage 236a shown in FIG. 3B. Accordingly, Moutafis et al teaches <u>away from</u> configuring the distal end opening 236a in a manner blocking passage of a stylet through the tube 214 and outwardly through the opening 236a. Because of this, it would be improper to combine the Moutafis et al reference with the Fogarty et al reference in the manner proposed by the Examiner.

For at least the foregoing reasons it is respectfully submitted that none of applicants' Claims 1-5 is rendered obvious by the Fogarty et al/Moutafis et al reference combination being proposed by the Examiner.

Via independent Claim 7, each of applicants' Claims 7-9 and 12-15 specifies that a recited inner elongated body portion of a catheter tube assembly has an open distal end configured to prevent movement of a recited stylet outwardly therethrough, the open distal end being in communication with an inner body lumen of the inner elongated body portion such that a substance introduced into a proximal opening of the inner body passes through the inner body lumen and is discharged from the tool through the distal opening of the inner body.

As discussed above relative to independent Claim 1, neither of the Fogarty et al and Moutafis et al references teaches or in any manner suggests a distal end opening of a catheter body through which a substance may be flowed outwardly from an interior lumen into an interior body region and which is also configured to prevent outward movement of a stylet therethrough, and Moutafis et al teaches away from making the Fogarty et al/Moutafis et al reference combination. It is thus respectfully submitted that none of applicants' Claims 7-9 and 12-15 is rendered obvious by the Fogarty et al/Moutafis et al reference combination being proposed by the Examiner.

3. The 35 USC §103(a) Rejection of Claims 7 and 10 Based On Vargas, III In View Of Fogarty et al and Moutafis et al

Via independent Claim 7, each of applicants' Claims 7 and 10 specifies that a recited inner elongated body portion of a catheter tube assembly has an open distal end configured to prevent movement of a recited stylet outwardly therethrough, the open distal end being in communication with an inner body lumen of the inner elongated body portion such that a substance introduced into a proximal opening of the inner body passes through the inner body lumen and is discharged from the tool through the distal opening of the inner body.

On page 5 of the August 11, 2010 Final Office Action the Examiner acknowledges that:

Vargas, III lacks a stylet having a proximal end and being sized and shaped for passage through the inner body lumen and adapted to straighten the expandable structure during deployment and the inner body having an open distal end allowing introduction of a substance therethrough while preventing movement of the stylet outwardly therethrough.

The Examiner seeks to cure these admitted deficiencies using the Fogarty et al and Moutafis et al references. However, as discussed above with respect to Claim 1, neither of the Fogarty et al and Moutafis et al references teaches or in any manner suggests a distal end opening of a catheter body through which a substance may be flowed outwardly from an interior lumen into an interior body region and which is also configured to prevent outward movement of a stylet therethrough, and Moutafis et al teaches away from combining Moutafis et al with the Fogarty et al reference. Thus, the Fogarty et al and Moutafis et al references clearly fail to cure the deficiencies in the Vargas, III reference.

It is thus respectfully submitted that neither of applicants' Claims 7 and 10 is rendered obvious by the Vargas, III/Fogarty et al/Moutafis et al reference combination proposed by the Examiner.

4. The 35 USC §103(a) Rejection of Claims 16-18 and 20 Based On Vargas, III In View Of Fogarty et al

Via independent Claim 16, each of applicants' Claims 16-18 and 20 specifies, as a portion of a tool for deploying an expandable structure into an interior body region, an expandable structure comprising a <u>first segment expandable to a generally spherical shape</u> and forming a first cavity, a <u>second segment expandable to a generally spherical shape</u> and forming a second cavity, and a joining section disposed between and interconnecting the first and second segments, the first expandable segment having a first expansion radius and the second expandable segment having a second expansion radius. Representatively, but not by way of limitation, applicants' claimed expandable structure may have the expanded configuration of the expandable structure 56 shown in applicants' drawing FIG. 12 in which the two generally spherical segments 82 and 84 of the expandable structure 56 are interconnected by a (generally tubular) joining section extending therebetween.

Neither Vargas, III nor Fogarty et al discloses or in any manner suggests an expandable structure having the above-noted expanded configuration set forth in applicants' Claims 16-18. Specifically, in Vargas, III FIGS. 20-24 relied upon by the Examiner it can clearly be seen that the inflated configuration of the balloon 1 is substantially **cylindrical**, and does not comprise first and second generally **spherical** segments interconnected by a joining section as specified in the present applicants' Claims 16-18 and 20. This expandable structure shape deficiency is in no manner cured by the Fogarty et al reference as may be readily seen in FIG. 3 showing the generally **cylindrical** inflated shape of the Fogarty balloon element 20.

For at least these reasons it is respectfully submitted that none of applicants' Claims 16-18 and 20 is rendered obvious by the Vargas, III/Fogarty et al reference combination proposed by the Examiner.

In view of the foregoing amendment, remarks and arguments, all of the claims currently pending in this application are now seen to be in a condition for allowance. A Notice of Allowance of Claims 1-5, 7-10, 12-18 and 20 is therefore earnestly solicited.

The Examiner is hereby requested to telephone the undersigned attorney of record at 972/739-8612 if such would further or expedite the prosecution of the instant application.

Respectfully submitted,

Attorney for Applicants Registration No. 28,867

Dated: OCTOBER 11, 2010

Haynes and Boone, LLP

2323 Victory Avenue, Suite 700

Dallas, Texas 75219

Telephone: 972/739-8612 IP Facsimile: 214/200-0853

Client Matter No. P0031798.155 | 41914.465

R-262526

Certificate of Service

mulle

thereby certify that this correspondence is being filed with the U.S. Parent and Trademark Office via EFS-Web on 10 Chapter 2010.

Saadia Cooks